wherein the introduced muscle-derived cells support and repair the injured or dysfunctional sphincter muscle.

- 82. (New) A method of bulking up muscle wall and enhancing muscle coaptation in impaired or dysfunctional muscle tissue, and organs, comprising:
  - (a) harvesting muscle-derived cells from an individual; and
- (b) introducing said muscle-derived cells into a site of muscle wall in an amount effective to bulk muscle wall and enhance muscle coaptation, wherein the introduced muscle-derived cells constitute a nonallergenic bulking agent providing support and bulk for the muscle wall.
- 83. (New) The method according to claim 81 or claim 82, further comprising: culturing the harvested muscle-derived cells under conditions allowing for their proliferation and/or differentiation prior to said introducing step (b).
- 84. (New) The method according to claim 81 or claim 82, wherein the musclederived cells in said introducing step (b) are primary muscle cells, cultured muscle cells, or cloned muscle cells.
- 85. (New) The method according to claim 81 or claim 82, wherein the muscle-derived cells are selected from the group consisting of fibroblasts, adipocytes, myoblasts, skeletal myoblasts, and muscle-derived stem cells.
- 86. (New) The method according to claim 85, wherein the muscle-derived cells are muscle-derived stem cells.
  - 87. (New)/The method according to claim 81 or claim 82, wherein the muscle-



derived cells are pluripotent muscle cells.

- 88. (New) The method according to claim 81 or claim 82, wherein the musclederived cells are genetically engineered to contain nucleic acid encoding a heterologous, bioactive gene product.
- 89. (New) The method according to claim 88, wherein the encoded bioactive gene product is selected from the group consisting of cytokines, trophic factors, growth factors, metabolic products, osteogenic products, serum proteins and hormones.
- 90. (New) The method according to claim §1, wherein the sphincter muscle is selected from the group consisting of urinary tract, muscle, urethra and bladder muscle.
- 91. (New) The method according to claim 82, wherein the muscle is selected from the group consisting of skeletal muscle, smooth muscle, sphincter muscle, urinary tract muscle, detrusor muscle, urethra and bladder muscle.
- 92. (New) A method of repairing injured or dysfunctional genitourinary tract muscle-or tissue, comprising:
  - (a) harvesting muscle-derived cells from a subject; and
- (b) introducing the harvested muscle-derived cells into the injured or dysfunctional genitourinary tract muscle or tissue in an amount effective to repair the injured or dysfunctional genitourinary tract muscle or tissue, wherein the introduced muscle-derived cells enhance coaptation and bulk of the genitourinary tract muscle or tissue.
  - 93. (New) The method according to claim 92, further comprising:

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culturing the harvested muscle-derived cells under conditions allowing for their proliferation and/or differentiation prior to said introducing step (b).

- 94. (New) The method according to claim 92, wherein the muscle-derived cells are pluripotent muscle cells.
- 95. (New) The method according to claim 92, wherein the muscle-derived cells are selected from the group consisting of fibroblasts, adipocytes, myoblasts, skeletal myoblasts, and muscle-derived stem cells.
- 96. (New) The method according to claim 95, wherein the muscle-derived cells are muscle-derived stem cells.
- 97. (New) The method according to claim 92, wherein the muscle-derived cells in step (b) are primary muscle cells, cultured muscle cells, or cloned muscle cells.
- 98. (New) The method according to claim 92, wherein the muscle-derived cells are genetically engineered to contain nucleic acid encoding a heterologous, bioactive gene product.
- 99. (New) The method according to claim 98, wherein the encoded bioactive gene product is selected from the group consisting of cytokines, trophic factors, growth factors, metabolic products, serum proteins and hormones.
- 100. (New) The method according to claim 92, wherein the genitourinary tract muscle is selected from the group consisting of urinary tract muscle, urethra and bladder muscle.

101. (New) The method according to claim 92, wherein the genitourinary tract injury or dysfunction is selected from the group consisting of bladder inflammation, overactive bladder, impaired bladder contractility, urinary stress incontinence and erectile dysfunction.

102. (New) A method of treating a sphincter muscle injury or dysfunction, comprising: introducing muscle-derived cells into a site of sphincter muscle injury or dysfunction in an amount effective to provide long-term muscle transplantation to enhance and support repair of sphincter muscle injury or dysfunction.

103. (New) A method of bulking up muscle wall and enhancing muscle coaptation in impaired or dysfunctional muscle tissue, and organs, comprising: introducing muscle-derived cells into a site of muscle wall in an amount effective to bulk muscle wall and enhance muscle coaptation, wherein the introduced muscle-derived cells constitute a bulking agent providing support and bulk for the impaired or dysfunctional muscle wall.

104. (New) The method according to claim 102, wherein the muscle-derived cells are harvested from an individual undergoing said muscle treatment.

105. (New) The method according to claim 103, wherein the muscle-derived cells are harvested from an individual undergoing said muscle wall bulking.

106. (New) The method according to claim 104 or claim 105, wherein said harvested muscle-derived cells are cultured under conditions allowing for their proliferation and/or differentiation prior to introduction into said site.

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107. (New) The method according to claim 102 or claim 103, wherein the muscle-derived cells are allogeneic to an individual receiving said cells.

- 108. (New) The method according to claim 102 or claim 103, wherein the muscle-derived cells are histocompatibly matched with the individual receiving said cells.
- 109. (New) The method according to claim 102 or claim 103, wherein the muscle-derived cells are pluripotent.
- 110. (New) The method according to claim 102 or claim 103, wherein the muscle-derived cells are selected from the group consisting of fibroblasts, adipocyte, myoblasts, skeletal myoblasts, and muscle-derived stem cells.
- 111. (New) The method according to claim 110, wherein the muscle-derived cells are muscle-derived stem cells.
- 112. (New) The method according to claim 102 or claim 103, wherein the muscle-derived cells are primary muscle cells, cultured muscle cells, or cloned muscle cells.
- 113. (New) The method according to claim 102 or claim 103, wherein the muscle-derived cells are genetically engineered to contain nucleic acid encoding a heterologous, bioactive gene product.
- 114. (New) The method according to claim 113, wherein the encoded bioactive gene product is selected from the group consisting of cytokines, trophic factors, growth

factors, metabolic products, serum proteins and hormones.

115. (New) The method according to claim 102, wherein the sphincter muscle is selected from the group consisting of urinary tract muscle, urethra and bladder muscle.

116. (New) The method according to claim 102, wherein the sphincter muscle injury or dysfunction is selected from the group consisting of bladder inflammation, overactive bladder, impaired bladder contractil urinary stress incontinence and erectile dysfunction.

117. (New) The method according to claim 103, wherein the muscle is selected from the group consisting of skeletal muscle, smooth muscle, sphincter muscle, urinary tract muscle, detrusor muscle, urethra and bladder muscle.

118. (New) Isolated muscle-derived stem cells produced according to any one of claims 76 to 80.

## <u>REMARKS</u>

In this Preliminary Amendment, new claims 81-118 have been added to more completely define the invention. Support for the new claims is found in the claims as originally filed. More specifically, support for the use of muscle-derived cells to bulk up muscle cell wall is found in the present specification at page 17, lines 5-11; at page 23, lines 17-25; page 61, lines 6-10. Support for suitable muscle-derived cell types is

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